JUL 2 2 2004

K041759

Attachment 1 – 510(k) Summary

Submitter Name:	ACE Surgical Supply Co., Inc.
Submitter Address :	1034 Pearl St., Brockton, MA 02301
Contact Person:	J. Edward Carchidi, DDS
Phone Number:	(508) 588-3100
Fax Number:	(508) 523-3140
Date Prepared:	June 2004
Device Trade Name:	ACE CONNECT™ Internal Connection Screw Dental Implant System
Device Common Name:	Screw Dental Implant
Classification Name:	Endosseous Dental Implant, product code DZE
Predicate device:	ACE Screw Dental Implant System, K954513
Reason for submission:	Not previously marketed in the USA

Device Description and Materials:
The ACE Surgical Internal Connection Screw Dental Implant System is a machined commercially pure titanium screw form implant intended to be implanted into the upper or lower jaw to serve as an anchor for a fixed dental prosthesis or single tooth restorations, constructed with an internal hexagon feature for inserting the implant into its surgical site, and to stabilize the prosthesis for rotational load, used to reconstruct the dentition of a patient who is wholly or partially edentulous, supplied in diameters of 3.75, 4.0, 4.75, and 5.75 mm, and in lengths of 8, 10, 11.5, 13, and 15 mm. The implant raw material is commercially pure titanium CP-4 as specified in ASTM F67-95 – Standard Specification for Unalloyed Titanium for Surgical Implant Applications. The implant surface is roughened by means of a blast media process to aid in implant adhesion. The candidate devices are identical in materials and characteristics to that cleared under K954513.

The ACE Surgical Internal Connection Screw Dental Implant System is a comprehensive system retaining prosthetic components, auxiliary components, and surgical tools as does the predicate ACE Surgical Screw Dental implant to assist with the implant's insertion and final prosthetic fabrication.

Intended Use:
The ACE Surgical Internal Connection Screw Dental Implant System is intended to be used in totally edentulous mandibles or maxillae or as a terminal or intermediary abutment for fixed or removable bridgework. The system can also be used for single tooth restorations. The indication/intended use of the modified device, the ACE Surgical Internal Connection Screw Dental Implant System, as described in its labeling has not changed from that of the predicates.

Substantial Equivalence/ Device Technological Characteristics and Comparison to Predicate Device(s):
The ACE Surgical Internal Connection Screw Dental Implant System is substantially equivalent to the ACE Surgical Screw Dental Implant System, K954513.

Among the information and data presented in the 510(k) submission to support the substantial equivalency of the ACE Surgical Internal Connection Screw Dental Implant System to the specified predicate devices are: 1) device description, 2) indications for use, 3) bench test results, 4) materials, and 5) labeling. In particular, the bench testing demonstrated there was no difference in the performance, safety, or effectiveness between the ACE Surgical Internal Connection Screw Dental Implant System and the specified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2 2004

Dr. J. Edward Carchidi
President
Ace Surgical Supply Company Limited
1034 Pearl Street
Brockton, Massachusetts 02301

Re: K041759
Trade/Device Name: ACE CONNECT™ Internal Connection Screw Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: June 28, 2004
Received: June 29, 2004

Dear Dr. Carchidi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041759

Device Name: ACE CONNECT™ Internal Connection Screw Dental Implant System

Indications for Use:

The ACE CONNECT™ Internal Connection Screw Dental Implant System is intended to be used in totally edentulous mandibles or maxillae or as a terminal or intermediary abutment for fixed or removable bridgework. The system can also be used for single tooth restorations.

Prescription Use ☞ X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K041759